

IN THE UNITED STATES PATENT AND TRADEMARKS OFFICE

In re Application of: Cagle et al.

Serial No: NYA
(Continuation Serial No. 10/200,868)

Confirmation No: NYA
(Continuation Confirmation No. 5897)

Filed: November 17, 2003

Examiner: NYA
(Continuation Application: Zohreh Fay)

Group Art Unit: NYA
(Continuation Application: 1614)

For: ANTIBIOTIC COMPOSITIONS FOR THE TREATMENT OF THE EYE, EAR
AND NOSE

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.56 AND §1.97(b)(1)

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §1.56, Applicants direct the attention of the Examiner to the sixty-six (66) references listed on the attached Form PTO-1449 (Sheets 1-6).

Applicants are submitting copies foreign patent documents and non-patent literature in accordance with 37 CFR 1.98(a)(2).

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with sufficient postage to the United States Postal Service as Express Mail EV 124 463 558 US, addressed to: Mail Stop Patent Applications, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date:

Date: November 17, 2003

Name: Deborah Weinschenk

Signature: Deborah Weinschenk

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Applicants request that the listed references be considered during prosecution of this application and made of record herein.

Respectfully submitted,
ALCON RESEARCH, LTD.

Date November 17, 2003

By Gregg C. Brown
Gregg C. Brown
Reg. No. 30,613

Enclosures: Form PTO-1449 (6 pages)
Foreign Patent Documents & Non-Patent Literature (35 references)

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Docket No. 1732 US F2

FORM PTO-1449 U.S. DEPT. OF COMMERCE Patent & Trademark Office		ATTY. DOCKET NO. <div style="text-align: center;">1732 US F2</div>		SERIAL NO. <div style="text-align: center;">NYA</div>	
LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT <div style="text-align: center;">Cagle et al.</div>			
		FILING DATE <div style="text-align: center;">November 17, 2003</div>		GROUP <div style="text-align: center;">NYA</div>	

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA1	4,474,751	10/02/84	Haslam et al.			
	AB1	4,551,456	11/05/85	Katz			
	AC1	4,670,444	06/02/87	Grohe et al.			
	AD1	4,710,495	12/01/87	Bodor			
	AE1	4,730,013	03/08/88	Bondi et al.			
	AF1	4,844,902	07/04/89	Grohe			
	AG1	4,920,120	04/24/90	Domagala et al.			
	AH1	4,980,470	12/25/90	Masuzawa et al.			
	AI1	4,990,517	02/05/91	Petersen, et al.			
	AJ1	4,996,335	02/26/91	Bodor			
	AK1	5,059,597	10/22/91	Petersen et al.			

FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AL1	CA 2,086,914	07/11/93	Canada			X	
	AM1	EP 0 982 031	03/01/00	Europe			X	
	AN1	ES S/N 08320	04/20/93	Spain				X
	AO1	WO 90/01933	03/08/90	WIPO			X	
	AP1	WO 96/39146	12/12/96	WIPO			X	

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)	
	AR1 Blondeau, Joseph M., "A review of the comparative in-vitro activities of 12 antimicrobial agents, with focus on five new 'respiratory quinolones', <u>Journal of Antimicrobial Chemotherapy</u> , vol. 43, Suppl. B, pages 1-11 (1999)
	AS1 Elies, W., "Newer fluoroquinolones in the treatment of ENT infections", <u>Chemotherapie Journal</u> , 7/3, pages 93-97 (1998) (no translation); XP000892813
	AT1 Ernst et al., "Levofloxacin and trovafloxacin: The next generation of fluoroquinolones?", <u>Clinical Review, Am. J. Health-Syst. Pharm.</u> , vol. 54, pages 2569-2584 (11/15/97)

EXAMINER

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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

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U.S. PATENT DOCUMENTS								
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	AA2	5,149,694	09/22/92	Cagle et al.				
	AB2	5,164,402	11/17/92	Brighty				
	AC2	5,185,337	02/09/93	Fujii, deceased et al.				
	AD2	5,223,493	06/29/93	Boltralik				
	AE2	5,416,096	05/16/95	Petersen et al.				
	AF2	5,480,879	01/02/96	Petersen et al.				
	AG2	5,520,920	05/28/96	Castillo, et al.				
	AH2	5,540,930	07/30/96	Guy et al.				
	AI2	5,563,138	10/08/96	Ueda et al.				
	AJ2	5,597,560	01/28/97	Bergamini et al.				
	AK2	5,607,942	03/04/97	Petersen et al.				
FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AL2	WO 98/06435	02/19/98	WIPO			X	
	AM2	WO 99/15172	04/01/99	WIPO			X	
	AN2	WO 00/18386	04/06/00	WIPO			X	
	AO2	WO 00/18387	04/06/00	WIPO			X	
	AP2	WO 00/18388	04/06/00	WIPO			X	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)								
	AR2	Gootz et al., "Fluoroquinolone antibacterials: SAR mechanism of action, resistance, and clinical aspects", <u>Medicinal Research Reviews</u> , vol. 16, pages 433-486 (1996)						
	AS2	Kaw et al., "The penetration of trovafloxacin into the eye and CSF of rabbits", IOVS, vol. 40, no. 4, page S88 (03/15/1999); XP-000892619						
	AT2	Kraseman et al., "Efficacy of Moxifloxacin against Staphylococcus aureus in respiratory tract and skin and skin structure infections", <u>Jornal Of Antimicrobial Chemotherapy</u> , vol. 44, no. Suppl. A, pp 150 (7/99); XP000892776						

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	AA3	5,631,004	05/20/97	Cagle et al.				
	AB3	5,665,373	09/09/97	Robertson et al.				
	AC3	5,679,665	10/21/97	Bergamini et al.				
	AD3	5,849,752	12/15/98	Grunenberg et al.				
	AE3	5,854,241	12/29/98	Hallenbach et al.				
	AF3	5,912,255	06/15/99	Bussell				
	AG3	6,093,417	07/25/00	Petrus				
	AH3	6,440,964	08/27/02	Cagle, et al.				
	AI3	6,509,327	01/21/03	Cagle, et al.				
	AJ3							
	AK3							
FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AL3	WO 00/18404	04/06/00	WIPO			X	
	AM3	EP 1 025 846	08/90/00	Europe			X	
	AN3	WO 01/45679	06/28/01	WIPO				X
	AO3	WO 01/89495	11/29/01	WIPO			X	
	AP3							
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)								
	AR3	McLeod et al., "The effect of topical trovafloxacin in a rabbit streptococcus pneumoniae keratitis model", IOVS vol. 40, no. 4, page S689 (03/15/1999) XP-000892625						
	AS3	NCCLS Document M7-A4, "Methods for Dilution Antimicrobial Susceptability Tests for Bacteria That Grow Aerobically", 4th Edition						
	AT3	"New Antimicrobial Agents Approved by the U.S. Food and Drug Administration in 1997 and New Indications for Previously Approved Agents" Antimicrobial Agents and Chemotherapy, vol. 42, no. 4, pages 987-988 (4/1/98); XP000872060						

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U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA4						
	AB4						
	AC4						
	AD4						
	AE4						
	AF4						
	AG4						
	AH4						
	AI4						
	AJ4						
	AK4						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	AL4						
	AM4						
	AN4						
	AO4						
	AP4						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AR4	NG et al., "Treatment of experimental staphylococcus epidermidis endophthalmitis with oral trovafloxacin" <u>American Journal of Ophthalmology</u> , vol. 216 (2), pages 278-287 (08/1998)					
	AS4	Patent Abstracts of Japan, vol. 1998, no. 10 (08/31/1998), JP 10 130148 05/19/1998 abstract					
	AT4	Patent Abstracts of Japan, vol. 012, no. 472 (12/09/1988), JP 63 190826 08/08/1988 abstract					

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	AA5						
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	AH5						
	AI5						
	AJ5						
	AK5						
FOREIGN PATENT DOCUMENTS							
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	AL5						
	AM5						
	AN5						
	AO5						
	AP5						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AR5	Pediatric Research, 104th Annual Meeting of the American Pediatric Society and the 63rd Annual meeting of the Society for Pediatric Research, vol. 35, no. 4, Part 2, page 191A, Seattle, Washington (05/02-05/94)					
	AS5	Senturia, Ben, "Etiology Of External Otitis", <u>Laryngoscope</u> , volume 55, pages 277-293 (1945)					
	AT5	Tillotson, G. S., "Quinolones: structure-activity relationships and future predictions", <u>J. of Medical Microbiology</u> , vol. 44, pages 320-324 (1996)					

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	AA6						
	AB6						
	AC6						
	AD6						
	AE6						
	AF6						
	AG6						
	AH6						

FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	A16							

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)		
	AJ6	Vincent et al., "Pharmacokinetics and safety of trovafloxacin in healthy male volunteers following administration of single intravenous doses of the prodrug, alatrofloxacin", <u>Journal of Antimicrobial Chemotherapy</u> , vol. 39, Suppl. B, pages 75-80 (01/01/1997)
	AK6	Weiss, Lee R., "Therapeutic Pathways for Antimicrobial Use: General Overview", <u>The American Journal Of Managed Care</u> , vol. 4, no. 10, Sup., pages S543-S549 (1988)
	AL6	Wentland, Mark P., "Structure-activity relationships of fluoroquinolones", <u>The New Generation of Quinolones</u> , (Siporin, C., Heifetz, C. L. & Domagala, J. M., Eds), pages 1-43, Marcel Dekker, New York (1990)
	AM6	Goldstein, et al., "In Vitro Activity of Bay 12-8039, a New 8-Methoxyquinolone, Compared to the Activities of 11 Other Oral Antimicrobial Agents Against 390 Aerobic and Anaerobic Bacteria Isolated from Human and Animal Bite Wound Skin and Soft Tissue Infections in Humans", <u>Antimicrobial Agents and Chemotherapy</u> , July 1997, pages 1552-1557
	AN6	Goldstein, et al., "Comparative In Vitro Activities of Azithromycin, Bay y 3118, Levofloxacin, Sparfloxacin, and 11 Other Orgal Antimicrobial Agents Against 194 Aerobic and Anerobic Bite Wound Isolates", <u>Antimicrobial Agents and Chemotherapy</u> , May 1995, pages 1097-1100
	AO6	Rubinstein, "Pharmacology - Tissue Distribution", <u>International Moxifloxacin Symposium, 1st (2000) Meeting date 1999</u> , pages 130-133; Editors: Mandell, Lionel

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